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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,202	08/08/2005	Todd M Boyce	525400-344	4795

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Carella Byrne Bain Gilfillan Cecchi
Stewart & Olstein
5 Becker Farm
Roseland, NJ 07068

EXAMINER	
KHOLDEBARIN, IMAN K	

ART UNIT	PAPER NUMBER
3737	

MAIL DATE	DELIVERY MODE
08/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,202	BOYCE ET AL.	
	Examiner	Art Unit	
	I Kenneth Kholdebarin	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/17/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent

2. Claims 1 as understood, is rejected under 35 U.S.C. 102(b) as being anticipated by D'urso et al. (US 5,741,215).

A variety of methods and apparatus for three dimensional modelling of articles including prosthetic implants are known. Many of these techniques employ digitised information from CAD-CAM design systems or data captured and/or reconstructed from a variety of reflection and/or transmission scanning devices.

Three dimensional coordinate data is obtained directly from the digital data generated by the computed tomographic information. The three dimensional coordinate data is then utilised to generate three dimensional cylindrical coordinates which are specified relative to an origin which is coincident with the origin of a coordinate system used in a sculpting tool apparatus to specify the spatial location of a cutting tool relative to a workpiece rotating on a turntable,(Col. 1, line 30-40).

3. Claims 1-13 as understood, is rejected under 35 U.S.C. 102(b) as being anticipated by White et al. (US 4,436,684).

Re Claim 1 and 4: A set of three dimensional coordinates defining a three dimensional representation of the selected internal structure is generated from the obtained representations and is employed to direct a sculpting tool to form a corporeal model of the selected structure. A model is formed from a workpiece of suitable material by operating the machine-controlled sculpting tool device to control the trajectory of its cutting sculpting tool relative to the workpiece in accordance with the coordinate data derived from the absorption coefficient representations of the structure obtained by the computerized x-ray tomographic device.

Re Claim 2-13: White discloses a method and the sytem where cutting plan is formulated from a computer based model; cut the bone manually or automated device; imaging step comprises

scanning by computed tomography; or MRI, (See Fig. 1-5B).

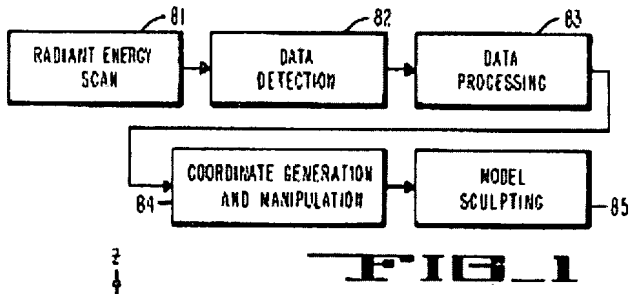

FIG_1

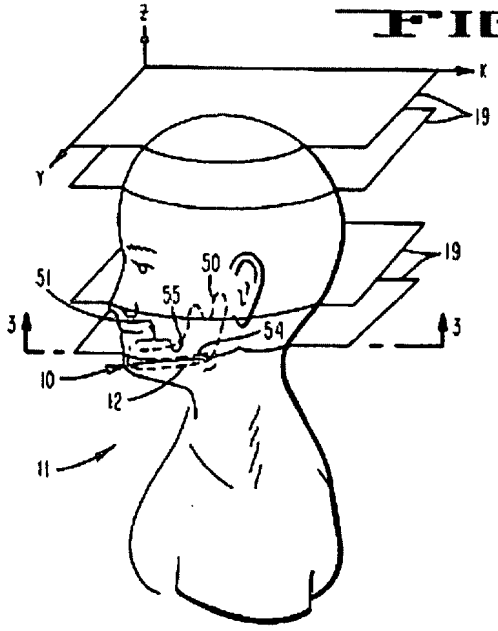

FIG_2

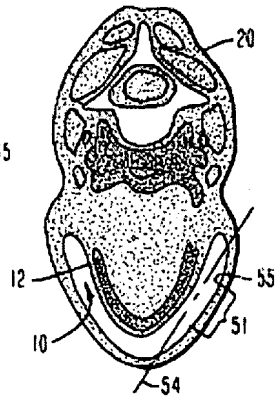

FIG_3

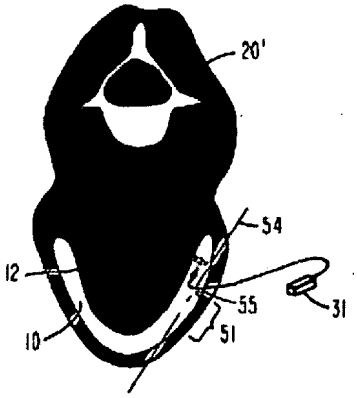

FIG_4

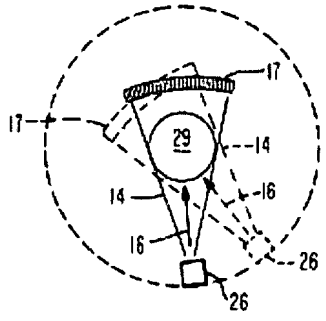

FIG_5A

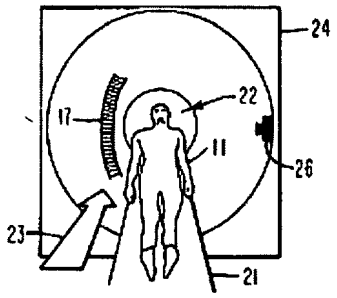

FIG_5B

Re Claim 14, 30 and 31: In mathematics, extrapolation is the process of constructing new data points outside a discrete set of known data points and morphometrics (from the Greek: "morph," meaning shape or form, and "metron", meaning measurement) comprises methods of extracting measurements from shapes; Therefore Claim 14 is anticipated by D'urso and white as following:

D'urso discloses A variety of methods and apparatus for three dimensional modelling of articles including prosthetic implants are known. Many of these techniques employ digitised information from CAD-CAM design systems or data captured and/or reconstructed from a variety of reflection and/or transmission scanning devices.

Three dimensional coordinate data is obtained directly from the digital data generated by the computed tomographic information. The three dimensional coordinate data is then utilised to generate three dimensional cylindrical coordinates which are specified relative to an origin which is coincident with the origin of a coordinate system used in a sculpting tool apparatus to specify the spatial location of a cutting tool relative to a workpiece rotating on a turntable, (Col. 1, line 30-40).

And furthermore, White discloses Re Claim 1 and 4: A set of three dimensional coordinates defining a three dimensional representation of the selected internal structure is generated from the obtained representations and is employed to direct a sculpting tool to form a corporeal model of the selected structure.

A model is formed from a workpiece of suitable material by operating the machine-controlled sculpting tool device to control the trajectory of its cutting sculpting tool relative to the workpiece in accordance with the coordinate data derived from the absorption coefficient representations of the structure obtained by the computerized x-ray tomographic device.

Re Claim 2-13: White discloses a method and the sytem where cutting plan is formulated from a computer based model; cut the bone manually or automated device; imaging step comprises scanning by computed tomography; or MRI, (See Fig. 1-5B).

Claims 24-29 as understood, is rejected under 35 U.S.C. 102(b) as being anticipated by Uchiyama[1]et al. (A Morphometric Comparison of Trabecular Structure of Human Ilium Between Microcomputed Tomography and Conventional Histomorphometry / Calcified Tissue International / Volume 61, Number 6 / December, 1997).

Uchiyama discloses: Recently, an imaging technique using microcomputed tomography (micro-CT) has emerged as a method for nondestructively assessing the microarchitecture of unprocessed surgical bone biopsy specimens. Using micro-CT, two-dimensional (2D) axial images were obtained from undecalcified transiliac bone biopsies which were taken from 15 patients with various metabolic bone diseases. Total area, bone area, and bone perimeter were determined, from which the bone volume (BV/TV), trabecular thickness (Tb.Th), trabecular number (Tb.N), and trabecular separation (Tb.Sp) were calculated semiautomatically and instantaneously. To evaluate the validity of this technique as a useful tool, the results were compared with those obtained from conventional histomorphometry. There were significant correlations between the two techniques for all parameters, with correlation coefficients ranging from 0.759 (Tb.N, $P < 0.005$) to 0.949 (BV/TV, $P < 0.0001$). Different resolutions seem to lead to major differences in perimeter values measured by the two methods. These factors may explain why the correlation coefficients of Tb.N and Tb.Th estimated from the perimeter and

area is lower than that of BV/TV. Our results show that the micro-CT based on 2D images is a useful tool for imaging and nondestructively quantifying the microarchitecture of trabecular bone in unprocessed surgical bone specimens.

Re Claim 32-36: White teaches obtaining the data for a bone implant assessing three dimensional measurements. As it mentioned earlier morphometrics (from the Greek: "morph," meaning shape or form, and "metron", meaning measurement) comprises methods of extracting measurements from shapes, (Fig. 1-5).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to I Kenneth Kholdebarin whose telephone number is 571-270-1347. The examiner can normally be reached on M-F 8 AM- 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IKK
Iman Kenneth Kholdebarin
08/01/2007

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700